

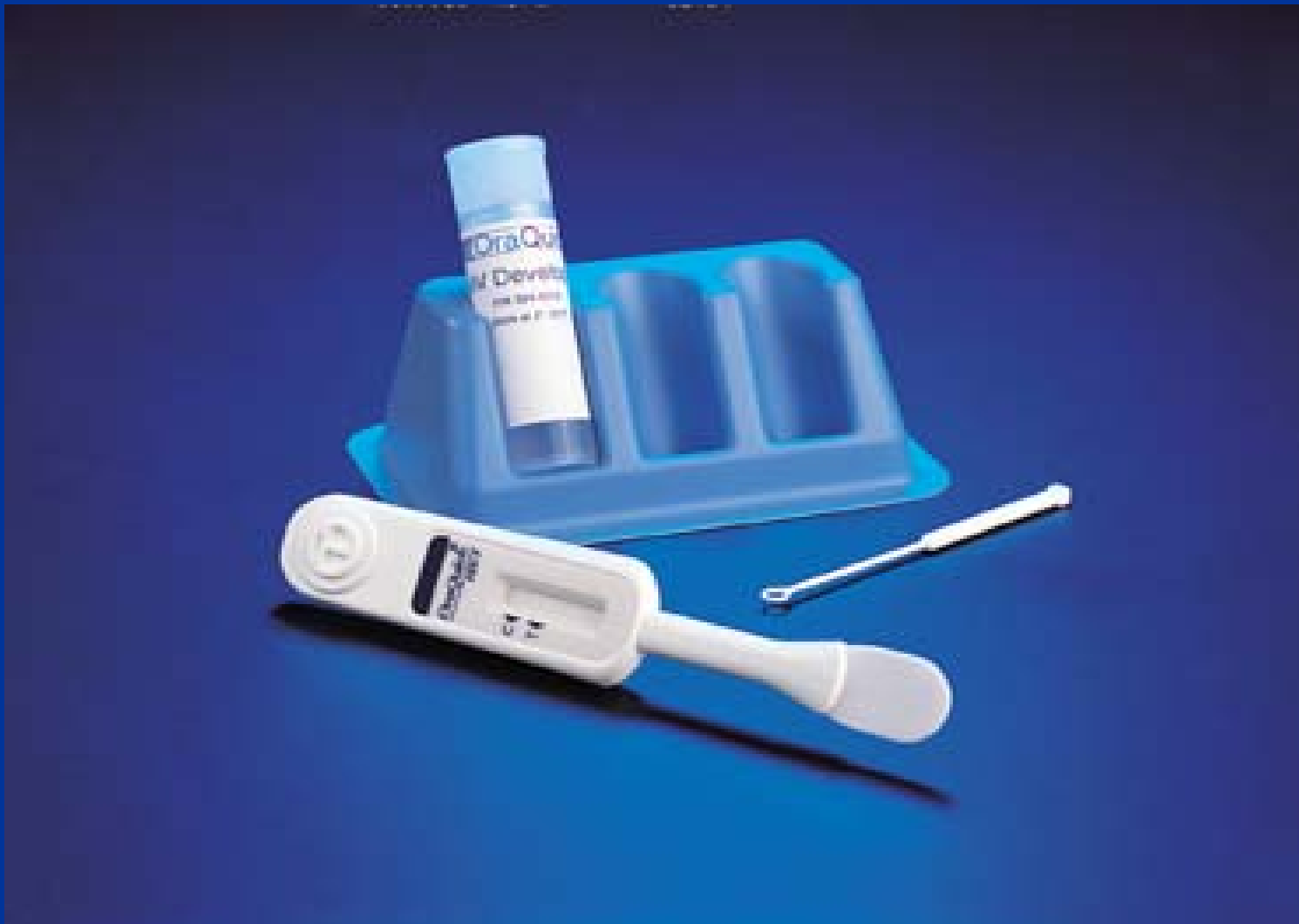
Update on Rapid HIV Testing

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Outline

- New FDA-approved rapid HIV tests
 - Characteristics
 - Requirements for use
- Point-of-care vs laboratory testing
- Challenges for interpreting HIV antibody test results



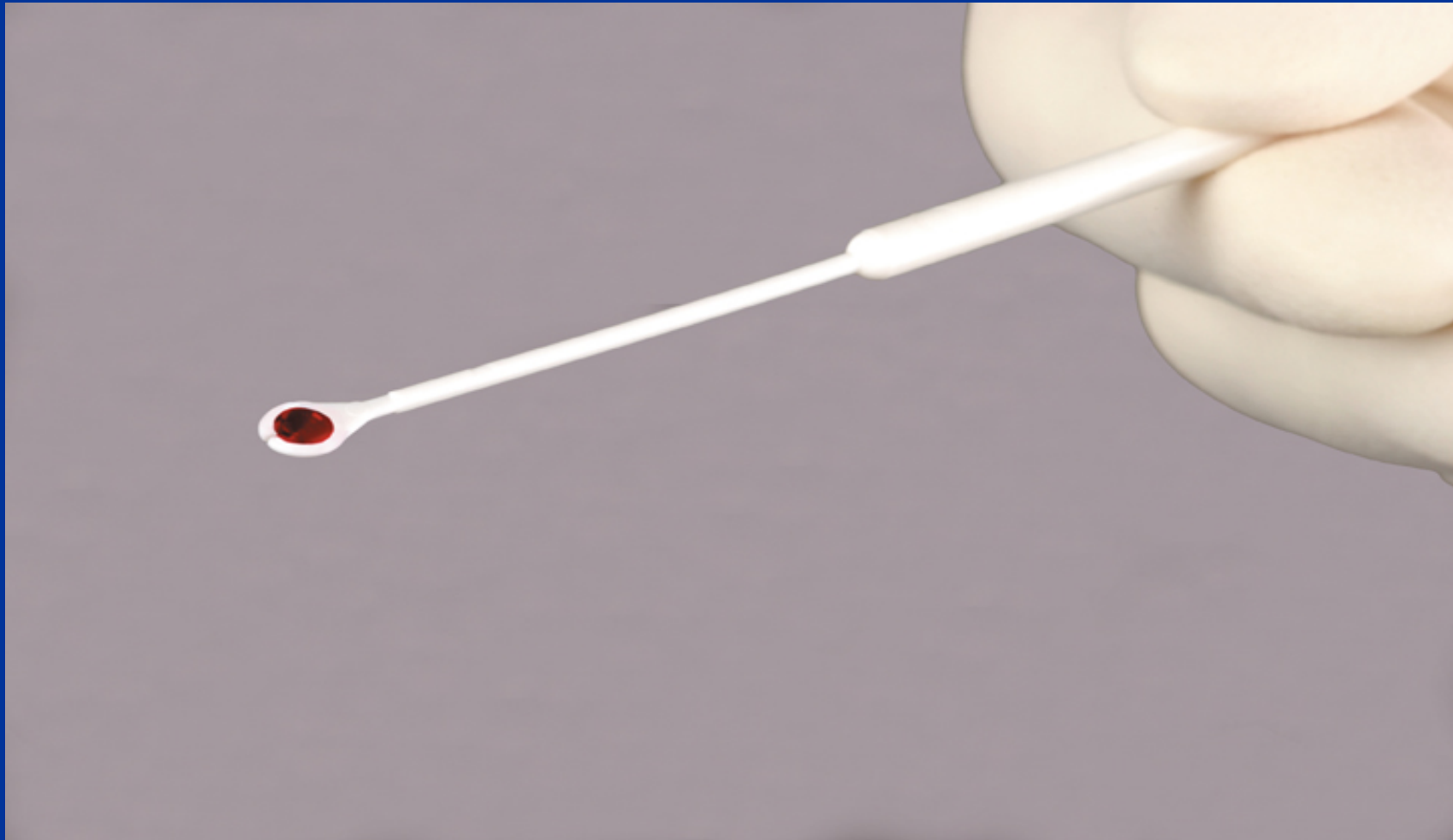
**OraQuick HIV-1 Rapid Antibody Test:
designed for oral fluid, serum, whole blood**



**FDA-approved November 7, 2002 for use with
finger stick whole blood specimens; granted
CLIA waiver January 31, 2003**



Obtain finger stick blood specimen



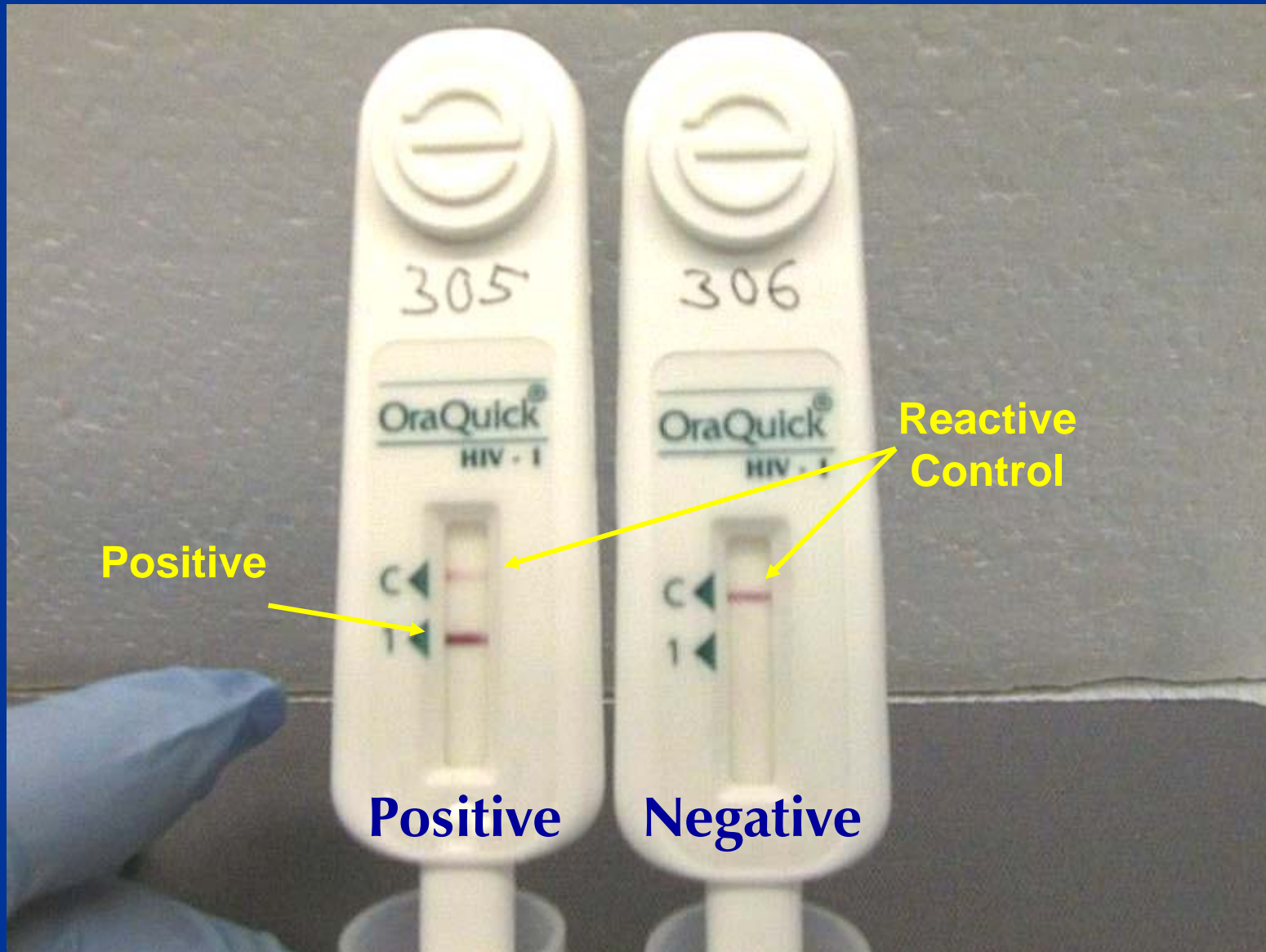
Loop collects 5 microliters of whole blood



Insert loop into vial and stir



Insert device; test develops in 20 minutes



Read results

OraQuick Characteristics

- Sensitivity 98.6% Specificity 100%
- CLIA waived
- Internal control
- Run external controls periodically
- Room temperature storage
- Suitable for point-of-care

Bethany Hospital

- Rapid test performed on Labor and Delivery unit.
- Eligible patients are determined here in the Labor and Delivery Triage area.



Provident Hospital



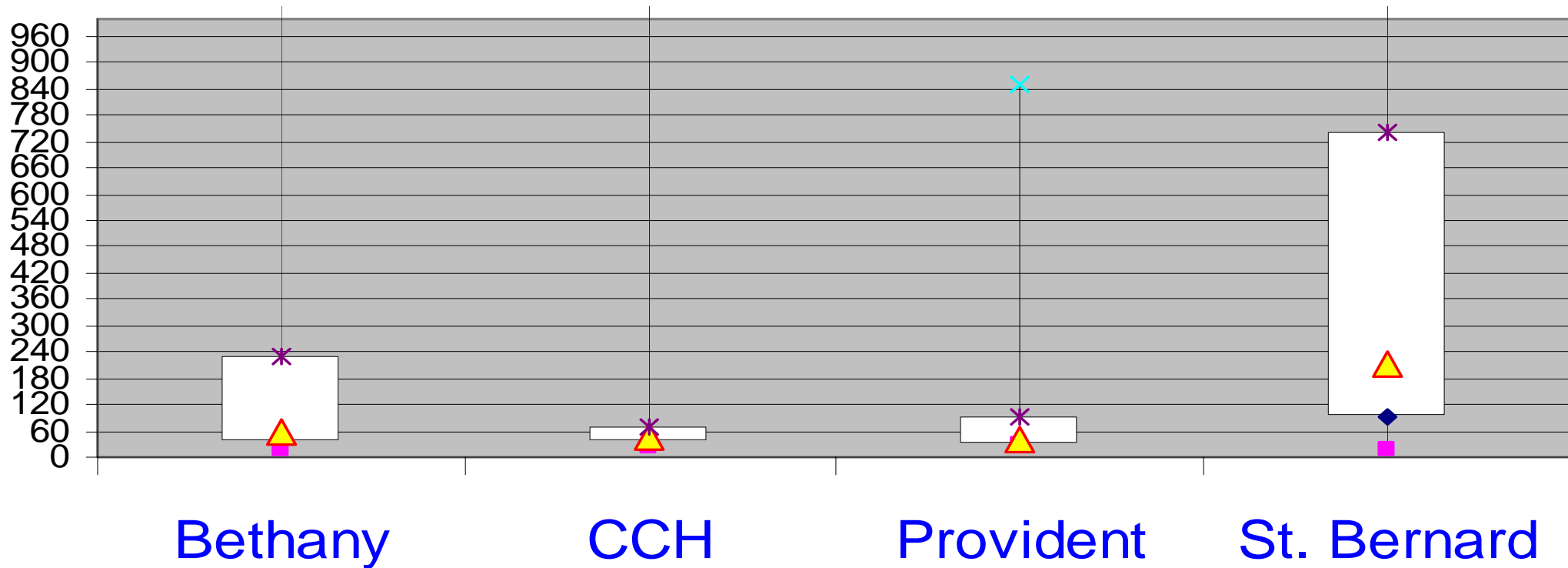
- The rapid test is done on this counter, extra supplies are stored below.
- OB physicians and Midwives share MIRIAD testing at Provident.

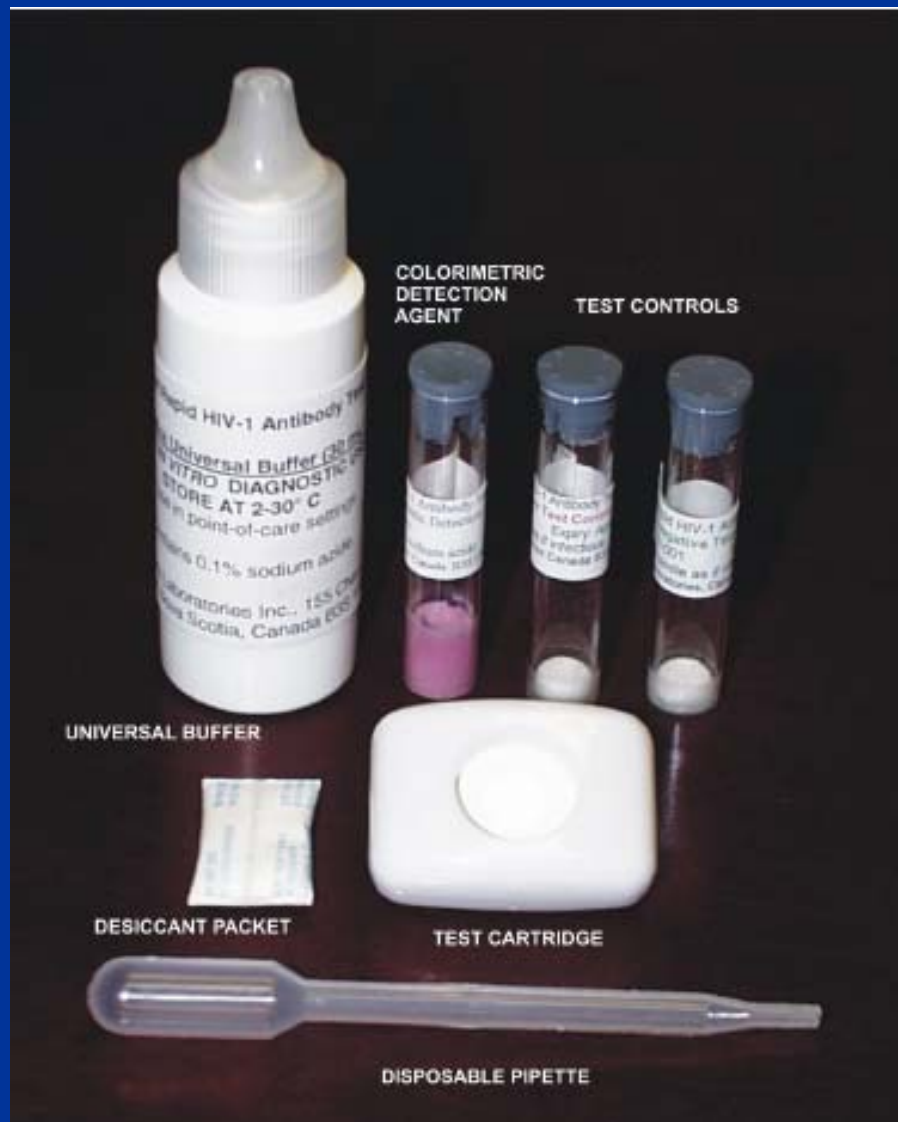
Cook County Hospital

- Clerks on each shift access HIV results from the computer system.
- Eligible patients are offered rapid testing and consented in the Triage area.



Boxplot of Turn Around Times





Reveal HIV-1 Rapid Antibody Test for serum, plasma
FDA approved April 16, 2003- Moderate Complexity



Centrifuge to obtain serum or plasma



**Add buffer to reconstitute conjugate and controls.
(Store refrigerated up to 7 days)**



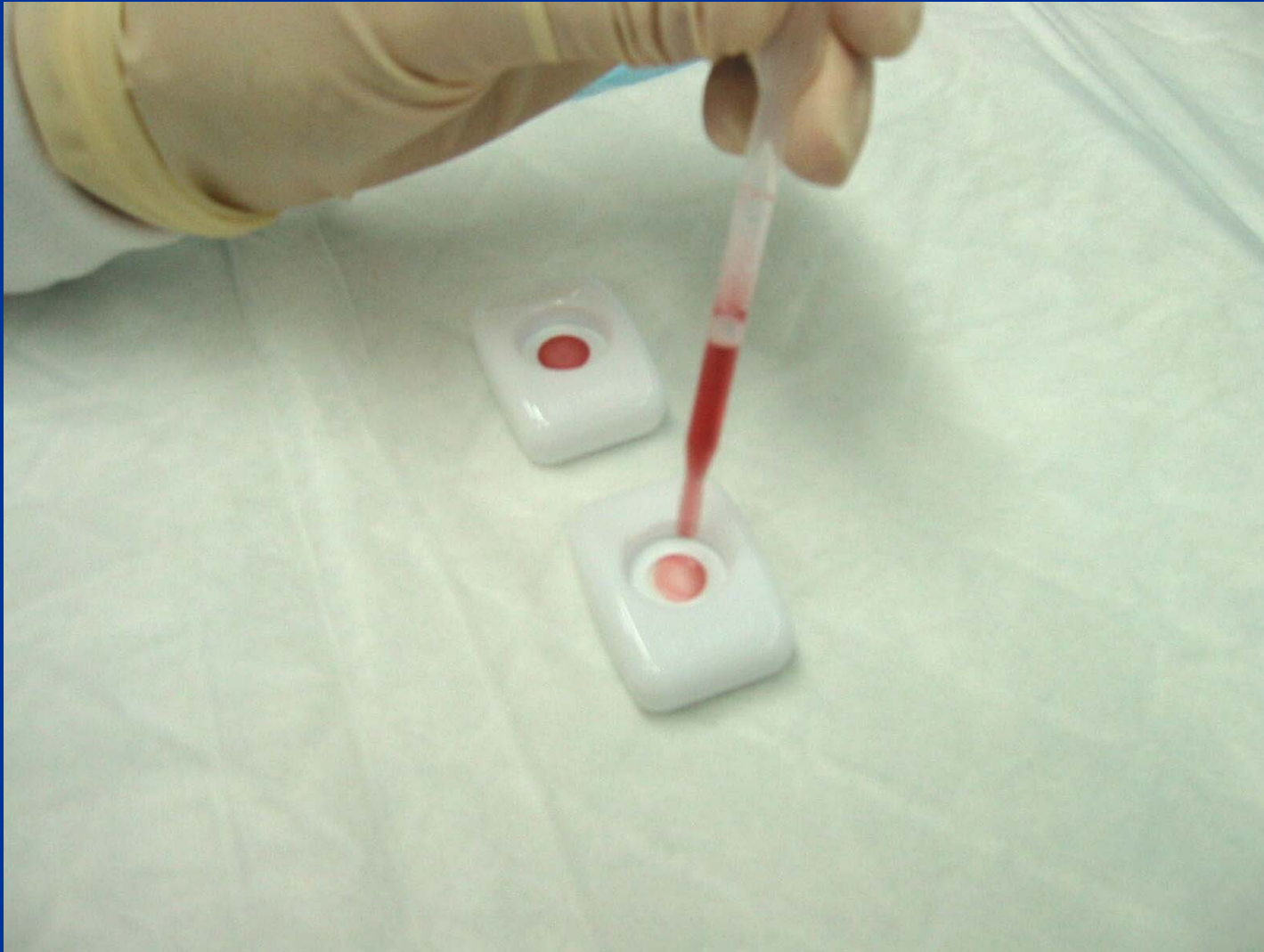
Add 3 drops buffer to moisten membrane



**Run positive and negative control with each test
or batch of tests**



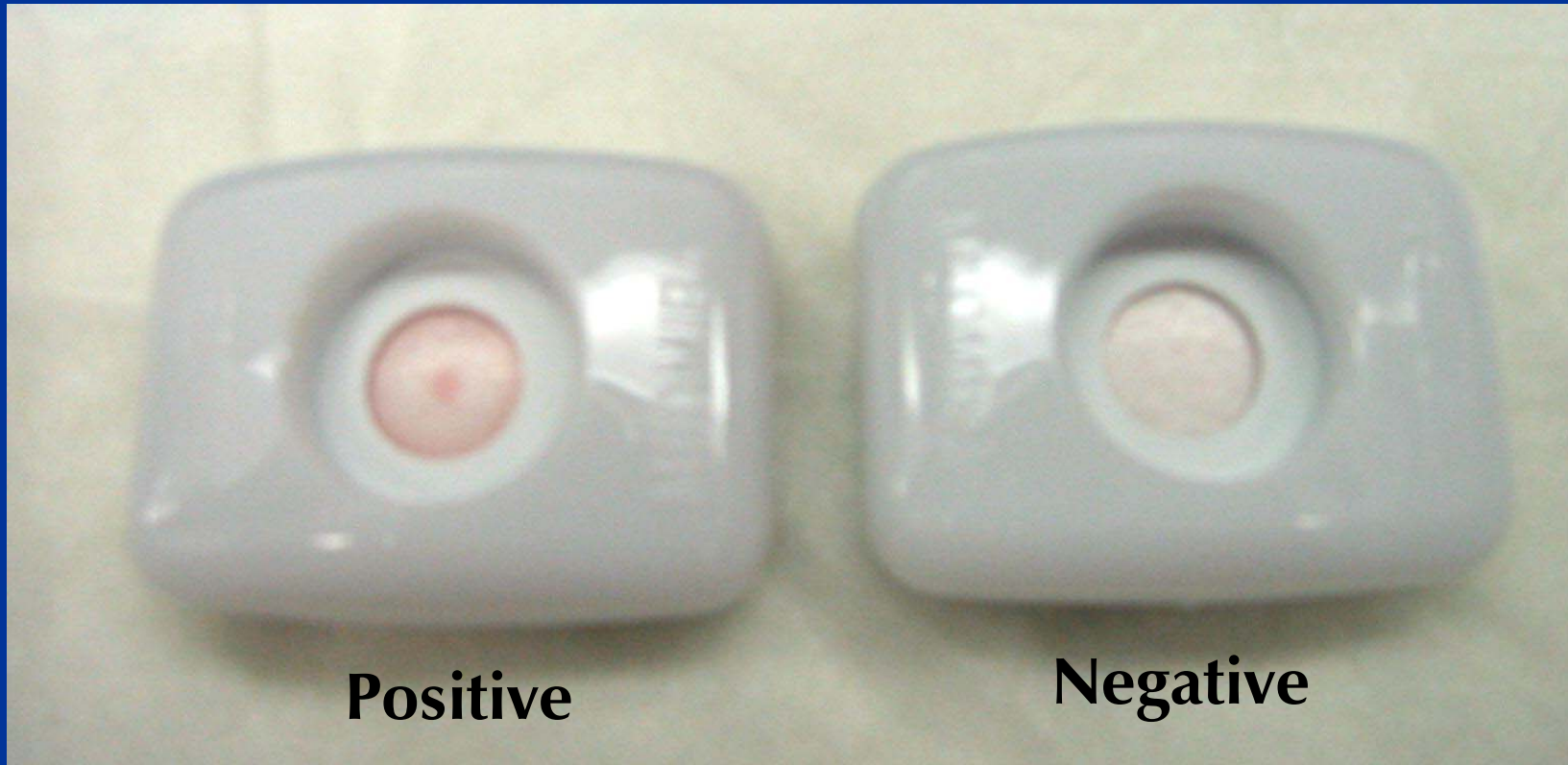
**Add one drop of serum or plasma, followed by
3 drops of buffer.**



Add 4 drops of conjugate solution



Add 3 drops of buffer to wash



Positive

Negative

Read results immediately

Reveal: Characteristics

- Sensitivity 98.8%
- Specificity: serum 99.1% plasma 98.6%
- CLIA: moderate complexity
- Run controls with each test
- Each vial of conjugate, controls sufficient for 5 tests
- Room temperature storage until reconstituted
- More dependent on laboratory facility

Rapid Test Performance: Serum

	<u>Sensitivity</u>	<u>Specificity</u>
OraQuick	100%	100%
Reveal	99%	100%
SUDS	97.9%	94.5%
HIV 1-2 EIA	-	95.1%

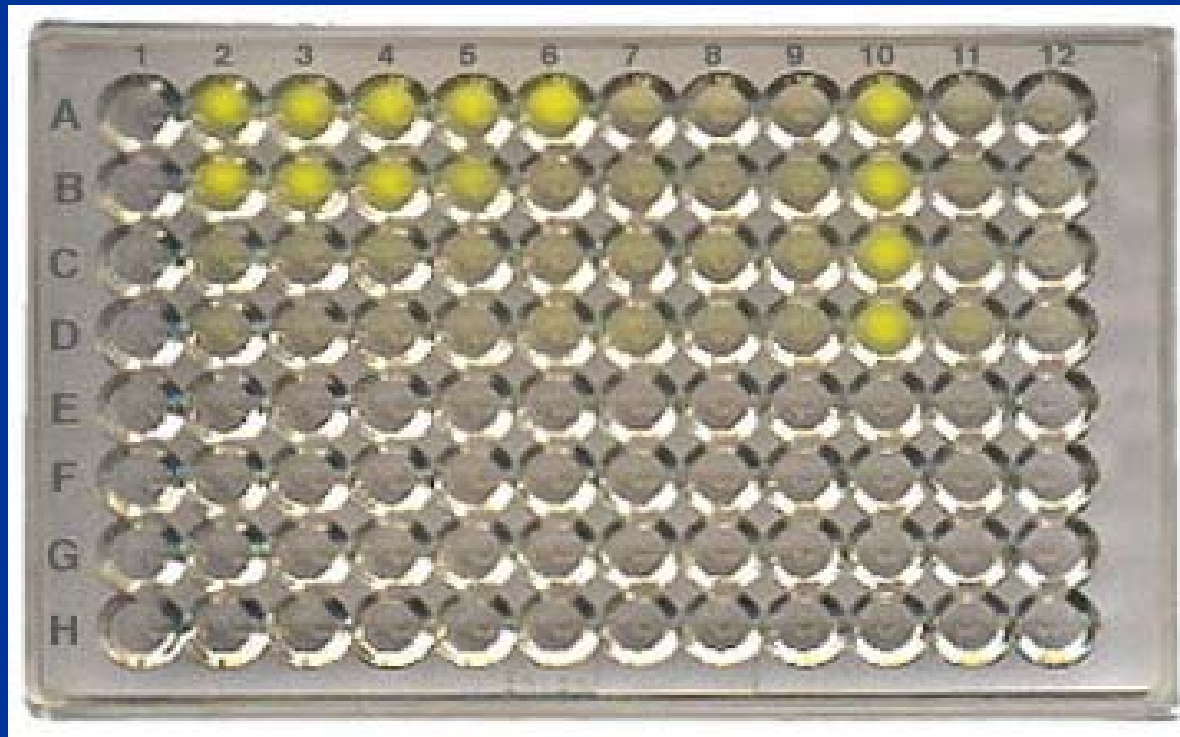
206 HIV+, 194 HIV- stored sera

Confirmatory Testing Required

- For Western blot:
 - Venipuncture for whole blood
 - Oral fluid specimen
- Immunofluorescence assay

New Opportunities For Confusion

Standard EIA



A color reaction occurs if HIV antibody is present

Standard tests: EIA



An automated reader gives an accurate measure of optical density (presence of color) for each well

Perinatal Screening: MIRIAD Study

- As of May:
 - 3178 women screened
 - 27 new HIV infections identified
 - 1 false-positive OraQuick; No false-negatives
 - 7 false-positive EIAs
 - 3 WB negative, 4 WB indeterminate
 - 3 false-positive SUDS
 - *(Theoretical: 27 false-positive Reveal)*

Challenge: Interpreting HIV Antibody Tests

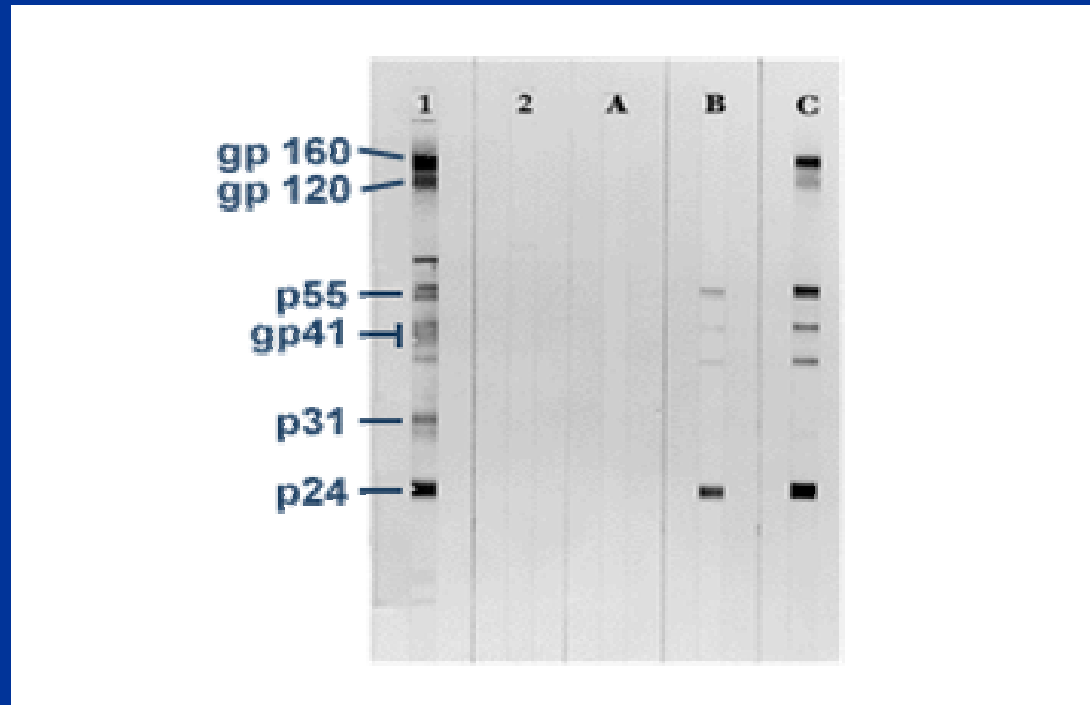
- 5 FDA-approved EIAs:
 - Abbott HIVAB HIV-1/HIV-2 (rDNA)
 - Genetic Systems HIV-1/HIV-2 Peptide
 - Genetic Systems rLAV HIV-1
 - Vironostika HIV-1 Microelisa
 - Vironostika HIV-1 plus O Microelisa*

**Approved June 6, 2003*

HIV Antigens in EIAs

Abbott HIVAB HIV-1/2	Gp41, Gp120, Gp36
Genetic Systems rLAV	Viral lysate, rGp41
Gen Sys HIV-1/HIV-2	Gp41, sP32, Gp36
Vironostika HIV-1 Microelisa	Viral lysate

Standard Confirmation: Western blot



Bands on the Western blot indicate which specific antibodies are present and can vary in intensity.

Western Blot Interpretation

- Negative: *No bands*
- Positive:
 - *Any two of: p24, gp41, gp120/gp160*
- Indeterminate:
 - *Presence of any bands not meeting criteria (frequently, only p24 or p55)*

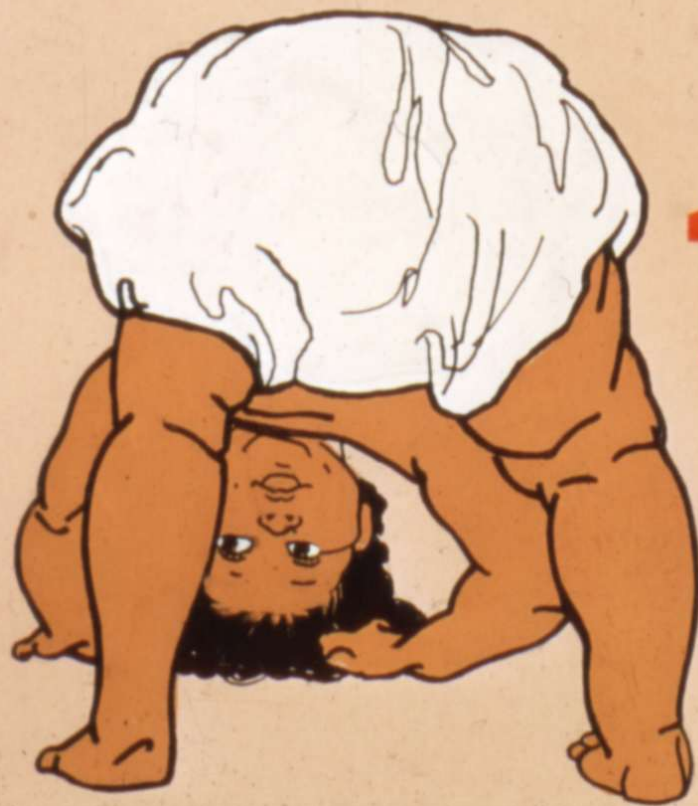
What to do?

- Become familiar with the tests that are used
- Choose tests carefully
- Ask for help!

Additional Resources

- Background information (updated frequently):

www.cdc.gov/hiv/testing.htm



the end